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PCT/IL 2005 / 000303

25 MAY 2005

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THE UNITED STATES OF AMERICA

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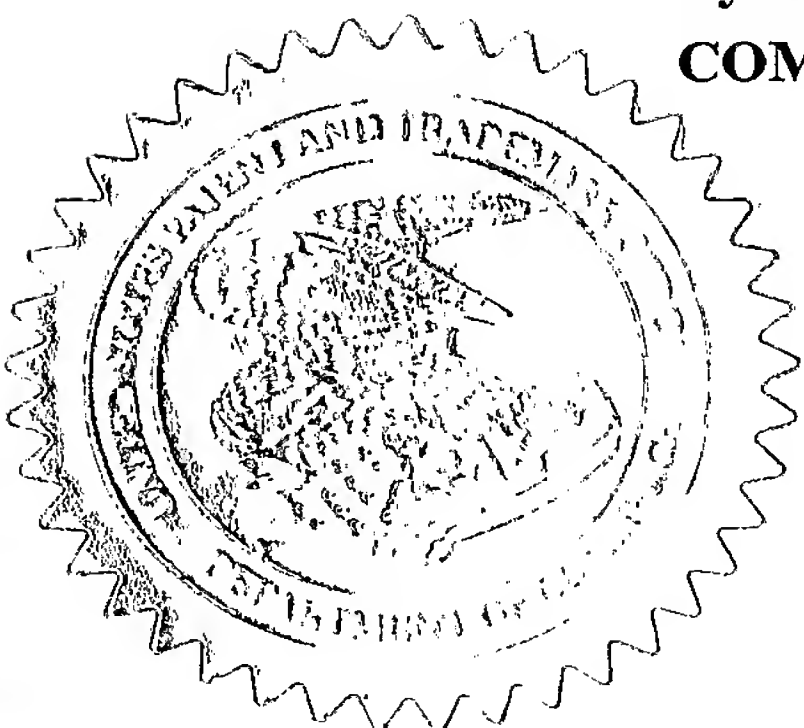
April 29, 2005

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APPLICATION NUMBER: 60/602,636

FILING DATE: August 19, 2004

**By Authority of the
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L. Edelen

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

22264 U.S. PTO
60/602636

081904

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
ELAN		ZIV MD		RAMAT-GAN, ISRAEL	
Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
A CIRCUMFERENTIAL RING FOR LIMITING INWARD MOVEMENT OF AN					
Direct all correspondence to:		CORRESPONDENCE ADDRESS			
<input type="checkbox"/> Customer Number:		APPLICATION FOR INSERTION OF TAMPONS, VARIOUS VAGINAL DEVICES AND INTRAVAGINAL DRUGS			
OR					
<input type="checkbox"/> Firm or Individual Name		DR. ELAN ZIV MD			
Address		8 HAILANOT STREET			
Address		GIVAT HABROSHIM			
City		RAMAT GAN		State	ISRAEL
Country		ISRAEL		Zip	52648
		Telephone	72-3-736966	Fax	72-3-736963
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		4		<input type="checkbox"/> CD(s), Number _____	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		1		<input type="checkbox"/> Other (specify) _____	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE Amount (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees.				<div>\$ 80</div>	
<input type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

[Page 1 of 2]

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME

TELEPHONE

Date

REGISTRATION NO.

(if appropriate)

Docket Number.

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27TOTAL AMOUNT OF PAYMENT (\$)
80

Complete if Known

Application Number

Filing Date

First Named Inventor

Examiner Name

Art Unit

Attorney Docket No.

D2. ELAN 214

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit
Account
Number
Deposit
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The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80
SUBTOTAL (1)				(\$)	80

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid
Independent	Multiple Dependent	-20** =	-3** =	X	X	

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

Name (Print/Type)

D2. ELAN 214

Registration No.
(Attorney/Agent)

(Complete if applicable)

Telephone 792-52-356928

Signature

Date 15.8.04

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**A CIRCUMFERENTIAL RING FOR LIMITING INWARD MOVEMENT OF AN
APPLICATOR FOR INSERTION OF TAMPONS, VARIOUS VAGINAL
DEVICES AND INTRAVAGINAL DRUGS**

5 The present invention relates generally to the field of intra- vaginal treatment of various conditions, such as infections, urinary incontinence, etc., in female patients. More specifically, the present invention relates to a vaginal applicator, intended for the correct placing of tampons, drugs, devices, etc., within the vaginal cavity.. The invention describes a vaginal applicator which is inserted in a no-self-touch technique, up to a
10 certain point in the vagina, with a circumferential ring marking the limit for insertion.

Inventor: Dr Elan Ziv, MD OBGYN, Urogynecologist

Background of the Invention

15 There are instances in medicine, in which a device should be applied into the vagina, but to a certain depth only, while retaining the full length of the applicator. In the case of vaginal devices used to treat urinary incontinence, it is imperative that one end of the device should be placed just under a predefined location within the vagina, such as the bladder neck or mid urethra. The device is inserted with an applicator, having its own
20 length which cannot be altered, thereby its extreme necessity to be accurate in its vaginal positioning. The exact positioning directly affects the efficacy of the device.

One possibility of solving the problem is by shortening the device and the applicator to the desired length, thereby a full insertion of the applicator (as is done with the insertion of a menstrual tampon) is performed. In some cases that solution is not applicable, hence
25 the need to mark the site which the application process should be stopped. One such possibility is by drawing a mark on the applicator which will instruct the user regarding the depth of insertion. Disadvantage of such method is by the fact that the user should be alert to the sign, and might miss it or forget to look for it. Another possibility is to add a raised mark on the applicator, so that the user's fingers are in direct contact with that
30 raised area, preventing the wrong length insertion of the applicator. That raised area could be a roughened area or a set of lines or a circumferential ring.

"A circumferential ring for limiting inward movement of a vaginal applicator for insertion of tampons, vaginal devices, and drugs"

Dr Elan Ziv, MD OBGYN, Urogynecologist

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While insertion of the applicator into the vagina, the user's fingers are held behind the ring, thereby marking the point for no further insertion. This will allow for a no-self-touch technique of insertion.

5 With different devices, for different intended uses, the ring should be placed in a different location along the applicator, as decided for this intended use. Dimensions of the ring might also alter according to intended use and to manufacturer's desire.

10 In some cases, the limiting ring might be part of the original molding by which the applicator was designed or manufactured. It is also possible to design an external body which will be fitted on top of the existing applicator, with the ring at the pre-defined dimensions and length from the margins. Such an external body may be made of a soft material such as silicone, or in some cases- of a harder material, such as polyethylene.

"A circumferential ring for limiting inward movement of a vaginal applicator for insertion of tampons, vaginal devices, and drugs"

Dr Elan Ziv, MD OBGYN, Urogynecologist

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The Invention

The present invention provides a means for controlling the depth of insertion of an applicator in order to place a vaginal device or drug into the predetermined proper position. One such condition for use is the intra-vaginal device for the treatment of urinary incontinence in females. When involuntary urination occurs, it is usually the result of the abnormal descent of the bladder neck and the urethra into a low position, away from the intra-abdominal pressure system. This "hypermobility" is the result of some injury to the support mechanism which normally keeps the urethra and the bladder neck in a raised position, along the backside of the pubic bone. The lowering of the bladder neck and the urethra that occur, for example, when a woman coughs, sneezes, or laughs, causes involuntary leakage of urine. The present invention is designed so as to provide a solution for putting a device exactly at the right spot where it should be in order to function correctly.

The invention will now be described with reference to accompanying drawing:

FIG. 1 is a side view of the applicator with the limiting ring.

The opening of the applicator (1) is located at the front side of the applicator, the first to be inserted. The body of the applicator (2) contains the tampon or the device or the drug to be applied into the vagina. The plunger (8) is designed to push the tampon or device or drug through the opening (1) into the vagina.

The limiting ring (4) is located at a predetermined length from opening (1). It might be part of the body of the applicator (2) or as a part of an external body (6) fitted externally on the body of the applicator (2)

Way of use:

The user inserts front edge of the applicator (1) into the vagina, gently pushing the body (2) inside until her fingers, located caudal to the limiting ring (4) come into touch with the external side of the labia. She then holds, and pushes the plunger (8) forward so as to push the inner content of the applicator into the vagina. The tampon or device is now in the right position and the applicator is disposed.

"A circumferential ring for limiting inward movement of a vaginal applicator for insertion of tampons, vaginal devices, and drugs"

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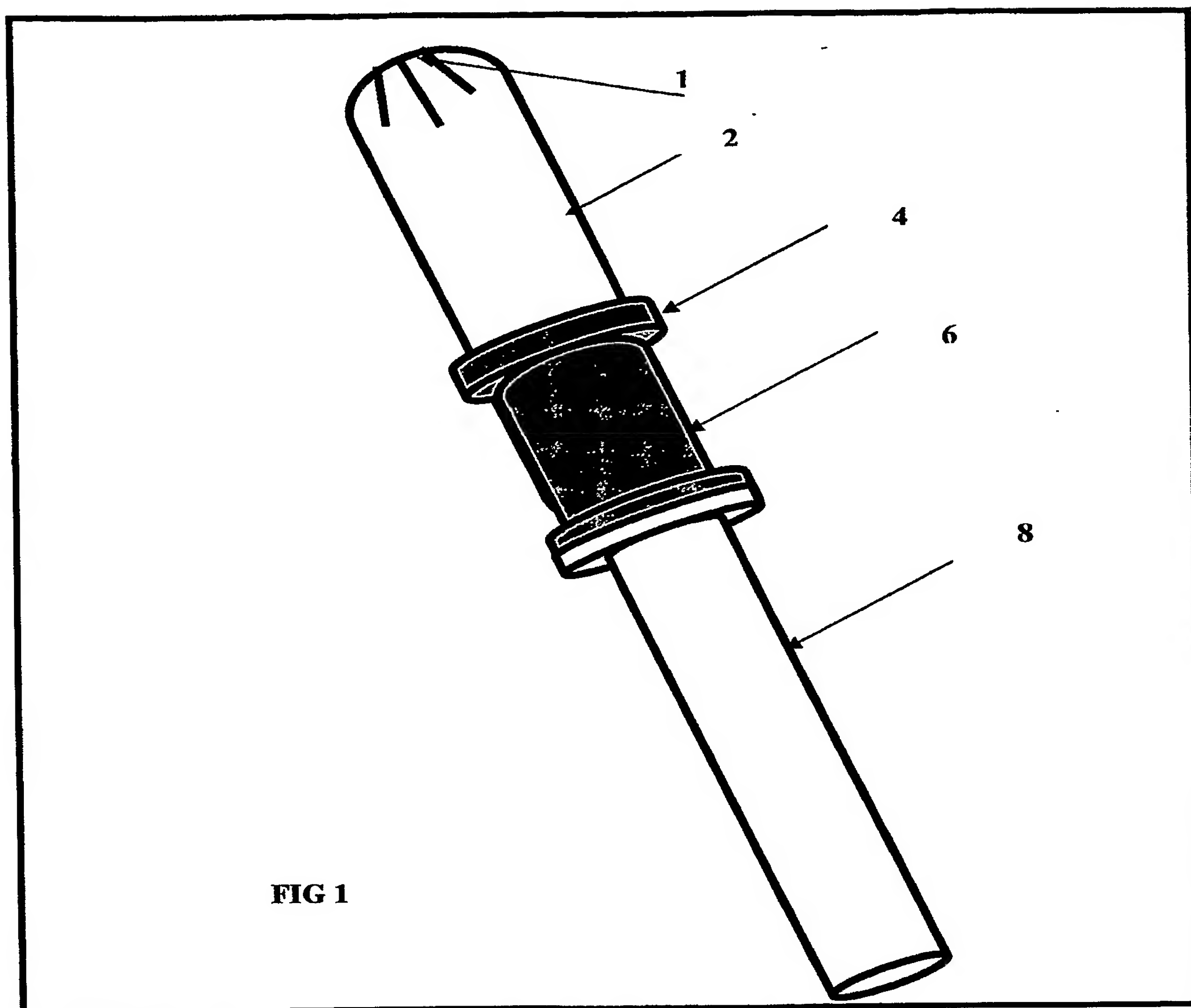
Alternative embodiments of the invention:

- It may be manufactured in different sizes
- It may be made of many flexible materials, such as silicone, polyurethane, etc.
- It may be made of several colors
- The applicator may be originally designed with the ring
- Length from the opening of the applicator may vary
- The invention may be used for other orifices in the body, such as the rectum, etc.

"A circumferential ring for limiting inward movement of a vaginal applicator for insertion of tampons, vaginal devices, and drugs"

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"A circumferential ring for limiting inward movement of a vaginal applicator for insertion of tampons, vaginal devices, and drugs"

Inventor: Dr Elan Ziv, MD OBGYN, Urogynecologist
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